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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY  
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WASHINGTON, D.C. 20231  
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OCT 18 2002

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Paper No. 16

In re Application of:	:	
Garvey et al	:	
Serial No.: 09/516,194	:	PETITION DECISION
Filing Date: March 1, 2000	:	
Attorney's Docket No.: 102258.285	:	

This is in response to "Petition from Restriction Requirement under 37 CFR 1.144" filed April 18, 2002, requesting the rejoinder and consideration of the additional species in pending claims 1-8, 10-17, 19-31, 33-40 and 104-106.

#### BACKGROUND

On May 8, 2001, the examiner made a restriction requirement to claims 1-115 and requested applicant to elect a single disclosed species. The restriction is as follows:

- Group I, claims 1-9, compounds of Formula I
- Group II, claims 10-115, composition comprising compounds of Formula I

The examiner stated that Groups I and II are related as product and process of use. Further, the examiner stated that in the instant case the compound may be used alone (I) or in combination (II). In addition, the examiner indicated that claims 1-4 and 10 are generic to polarity of disclosed patentably distinct species comprising, the compound, composition and method of use. The examiner required an election of a single disclosed compound, composition, and method of use.

Applicant replied by electing Group II, comprising a compound of Formula I and a vasoactive agent. Applicant traversed the election of species requirement and

provisionally elected nitrosated prostaglandins, Example 11, and presenting a structural formula thereof (i.e. prostaglandins containing at least one  $\text{-NO}_2$  group); and phentolamine as the species for the vasoactive agent. Applicant argued that the claims are directed to compounds and composition comprising prostaglandins, methods of use of the composition and kits for the composition. Applicant urged that if the compositions were allowable, then all the compounds of Formula I in those compositions would also be allowable. In addition, applicant argued that a search of the prior art for the compositions of Group II will also be the same prior art for the compounds of Formula I, i.e., Group I. Furthermore, applicant directed the examiner's attention to the search report of the corresponding PCT application. The examiner examined all the claims together and that all claims were found to be Novel, Inventive, and have Industrial Applicability.

On July 24, 2001, an Office action was mailed. The examiner accepted the election. The examiner indicated that applicant timely traversed the restriction (election) requirement. The compound, composition, method of treating sexual dysfunction and kit claims were examined to the extent they read on the elected prostaglandin nitrate containing esters. Claims 1, 9, 18, 32, 41-103, and 107-115 are withdrawn from further consideration as drawn to non elected inventions, there being no allowable generic or linking claim. Claim 1 was rejected under 35 USC 112, 2<sup>nd</sup> paragraph, and claims 2-8, 10-17, 19-31, 33-40, and 104-106 were objected to as being directed to a misjoinder of inventions. The examiner indicated that claims limited to the elected invention would be allowable.

On October 24, 2001, applicants requested examination of other species that fell within the scope of the compound of Formula I pursuant to MPEP 803.02.

On January 22, 2002, a final Office action was mailed. Claim 1 was withdrawn from further consideration. Claims 2-8, 10-17, 19-31, 33-40, and 104-106 remained objected to as being directed to a misjoinder.

On April 18, 2002, the present petition was filed, requesting reconsideration and reversal of the examiner's decision.

## DISCUSSION

Applicants argue that the examiner failed to consider nitro and nitroso substituted PGs that fall within the scope of the compound of Formula I. Applicants argue that the pending claims are all directed to the same invention. Claim 2 recites compounds of Formula I that are nitrosated prostaglandins (contain a  $\text{-NO}_2$  group); nitrosylated prostaglandins (contain a  $\text{-NO}$  group); and nitrosated and nitrosylated prostaglandins (contain a  $\text{-NO}_2$  group and a  $\text{-NO}$  group). Applicants argue that the examiner is required to consider the compounds of Formula I to the extent they cover nitrosated and nitrosylated prostaglandins (prostaglandins that contain a  $\text{-NO}_2$  group and a  $\text{-NO}$  group). Applicants argue that it is unfair for the examiner to refuse to consider compounds that contain both a  $\text{-NO}_2$  group and a  $\text{-NO}$  group, or compounds that contain a

-NO group. Applicants rely on MPEP 803.02 for their position. Applicants argue that the examiner's refusal to examine the additional species in claims 1-8, 10-17, 19-31, 33-40, and 104-106 in the pending application is improper.

The file history has been carefully reviewed. It appears that the examiner considered applicant's traversal and combined compound (prostaglandin nitrate containing esters), composition, and method of treating sexual dysfunction together for examination. However, the examiner did not outline the revised restriction.

Claims restricted to different species must be mutually exclusive. In making a requirement for restriction in an application claiming plural species, the examiner should group together species considered clearly unpatentable over each other. Election of species should not be required if the species claimed are considered clearly unpatentable (obvious) over each other. In the instant case, the examiner failed to identify the mutually exclusive species. Further, prostaglandins containing -NO<sub>2</sub> group do not necessarily exclude PGs containing -NO group, or vice versa. In the instant application in which no species claims are presented and a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required, the examiner properly required for an election of species prior to the search of the generic claim. However, the examination should have been extended the examination to determine patentability of the generic claim after indication of the allowability of the elected species.

In view of the above discussion, the examiner should have extended the search and examination after indication of the elected species is allowable.

#### DECISION

Applicants' petition is GRANTED.

**The application will be forwarded to the examiner for consideration of applicants' reply to the last Office action following mailing of this decision.**

Should there be any question with respect to this decision, please contact Cecilia Tsang, by mail addressed to: Director, Technology Center 1600, Washington, D.C. 20231, or by telephone at (703) 308-0254 or by facsimile transmission at (703) 308-3890.



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